UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,201	11/30/2001	Shoujun Chen	13321-007001	8537

26161 7590 05/01/2003

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER
JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
1615	10

DATE MAILED: 05/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/010,201	Applicant(s) CHEN ET AL.	
	Examin r Robert M. Joynes	Art Unit 1615	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of applicants' Information Disclosure Statements filed on November 8 and 13, 2002 and the Response filed on February 6, 2003.09-

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 and 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schutt (US 4248861). Schutt teaches a skin composition comprising Kava Kava and a carrier (Col. 3, lines 33-41, 48-68; Col. 4, lines 1-5; Col. 5, Examples 3 and 4). This composition is applied to the skin to treat burns and can be prepared in any desired manner and in any suitable order or sequence of addition of the various components (Col. 4, lines 31-44). The Kava Kava is present in amounts from 0.5 to 3 parts by weight (Col. 3, lines 33-41). Schutt further teaches that the Kava Kava extract

has an anesthetic effect (Col. 3, lines 33-41). It is the position of the Examiner that Kava Kava contains all the kavalactones claimed in the instant application.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of the kavalactones. With respect to the claimed concentrations, absent a clear showing of criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization.

One of ordinary skill in the art would have been motivated to do this to provide different dosage levels for different skins types or simply to adjust concentration according to what additional ingredients are included in the composition.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asmussen et al. (US 6379696) in combination with Elbakyan (WO 00/30578) further in combination with Schwabe (US 5296224) further in combination with Schutt. Asmussen teaches a transdermal therapeutic system comprising kawain (Col 3- 4, Claim 1).

Asmussen does not expressly teach the patch composition and components of the composition. Asmussen further does not expressly teach that the kawain is used to treat pain.

Elbakyan teaches a transdermal patch composition comprising an active agent in a polymer matrix (Page 6, lines 10-27), an absorbent layer wherein the active composition is supported and a nonabsorbent backing layer (Page 8, lines 13-30).

Elbakyan does not expressly teach a kavalactone as the active agent.

Schwabe teaches that kawain is a kavalactone. Schwabe further teaches other suitable kavalactones such as dihydrokawain, methysticin, dihydromethysticin and yangonin (Col. 1, lines 14-53). Schwabe does not expressly teach that the kavalactones treat pain.

The teachings of Schutt are discussed above. Briefly, Schutt teaches a topical composition comprising Kava Kava extract that contains the specific kavalactones and is used for its anesthetic effect.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a transdermal therapeutic system in the form of a transdermal patch comprising kavalactones for treating pain. Asmussen teaches kawain in a transdermal system. Elbakyan teaches the transdermal system can be in the form of a patch. Schwabe teaches the other suitable kavalactones. Schutt teaches the kavalactones can be used to treat pain.

One of ordinary skill in the art would have been motivated to do this to provide a slow-release therapeutic composition for topical administration in the treatment of skin conditions, whether it is burns or hypertrophic skin accumulations or pain.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments with respect to claims 1-35 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue that the Schutt reference does not teach a composition that comprises the specific kavalactones in the specific concentrations. Further applicants argue that Schutt does not teach a composition or ointment that treats pain. As stated above in this action, the determination of particular concentration ranges is within the skill of the art. The prior art teaches a composition comprising Kava Kava extract that contains all the kavalactones recited in the instant claims. Applicants have shown no unexpected results by selecting these three kavalactones in their particular concentrations. Absent a showing of unexpected results, the instant claims are rendered obvious over the prior art. As for the treatment of pain, the prior art clearly states that the Kava Kava extract has an anesthetic effect, which is interpreted as a treating pain.

Conclusion

Due to the new grounds for rejection, this Action is deemed Non-Final.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
April 28, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600